

K030679

**Summary of Safety and Effectiveness****FEB 05 2003**

**Submitter:** Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**Contact Person:** Fred McClure, RAC  
Sr. Associate, Regulatory Affairs  
Telephone: (574) 372-4294  
Fax: (574) 372-4605

**Date:** January 8, 2003

**Trade Name:** *VerSys® Beaded Fullcoat Bowed Revision Hip Prosthesis*

**Common Name:** Total hip prosthesis

**Classification Name and Reference:** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis  
21 CFR § 888.3358

**Predicate Device:** *VerSys Hip System Beaded Hip Prosthesis*, manufactured by Zimmer, K973714, cleared December 24, 1997

**Device Description:** Like its predicate, the *VerSys Beaded Fullcoat Bowed Revision Hip Prosthesis* is a modular femoral stem manufactured from Co-Cr-Mo alloy and has a sintered Co-Cr-Mo alloy bead porous surface coating. The prosthesis features a 12/14 Morse-type proximal neck taper to mate with the corresponding 12/14 bore of a femoral head component. Proximal body geometry of the prosthesis is trapezoidal.

**Intended Use:** The *VerSys® Beaded Hip Prosthesis* is designed to achieve biologic fixation to bone and is indicated for:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis,



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 05 2003

Fred McClure, RAC  
Sr. Associate, Regulatory Affairs  
Zimmer, Inc.  
P.O. Box 708  
Warsaw, Indiana 46581-0708

Re: K030079

Trade/Device Name: VerSys® Beaded Fullcoat Bowed Revision Hip Prosthesis

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip Joint Metal/Polymer/Metal Semi-constrained Porous-coated  
Uncemented Prosthesis

Regulatory Class: Class II

Product Code: LPH

Dated: January 8, 2003

Received: January 9, 2003

Dear Mr. McClure:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 – Mr. Fred McClure

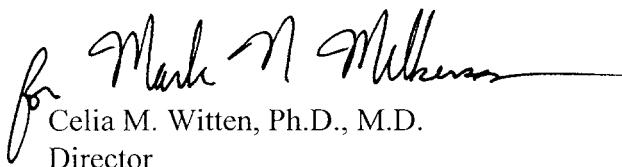
CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Mark N. Miller

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

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510(k) Number (if known): K030079

**Device Name:**

VerSys® Beaded Fullcoat Bowed Revision Hip Prosthesis

**Indications for Use:**

The VerSys Beaded Hip Prosthesis is designed to achieve biologic fixation to bone and is indicated for:

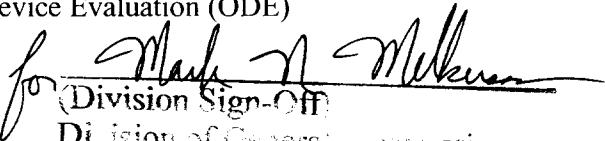
Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusion acetabuli, slipped capital femoral epiphysis, disability due to previous fusion, previously failed endoprostheses and/or total hip components in the affected extremity, and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip, elderly, debilitated patients when a total hip replacement is contraindicated, irreducible fractures in which adequate fixation cannot be obtained, certain high subcapital fractures and comminuted fractures, secondary avascular necrosis of the femoral head, pathological fractures of the femoral neck, and osteoarthritis in which the femoral head is primarily affected.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division Sign-Off  
Division of General and Diagnostic  
and Neurological Devices

510(k) Number K030079

Prescription Use Y  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use N  
(Optional Format 1-2-96)